510(k) Summary of Safety and Effectiveness

K002590

Submitter:	Cedara Software Corporation
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Carol Nakagawa.
Telephone:	(905) 672-2100.
Date:	August 18, 2000.
Trade Names:	Cedara Cardiology Viewer; Cardiology Archive Viewer; Cardiology CD Viewer
Common Name:	Image processing software for cardiology.
Classification Name:	Picture archiving and communications system.
Predicate Devices:	DICOMview® from Heartlab, Inc., Cardiovascular Workstation, Model CWS 5000/CWS 3000 from Infimed, Inc. and Medical Imaging Family of Workstations (MIFW) from I.S.G. Technologies, Inc.
Device Description:	The Cedara Cardiology Viewer software is a product line extension of Cedara's (formerly I.S.G. Technologies, Inc.) medical image processing workstation product, "Medical Imaging Family of Workstations". The Cedara Cardiology Viewer is a software accessory that will be typically used for cardiology applications and consists of features that allow the qualified medical professional to control image capture and to retrieve, display, manipulate, measure, report and save medical images generated by a variety of imaging sources such as ultrasound, magnetic resonance angiography, etc.
Intended Use:	The Cedara Cardiology Viewer software allows qualified medical professionals to capture, retrieve, display, manipulate, measure, report, and save cardiac or other medical images generated by a variety of imaging sources such as X-ray angiography (XA), echocardiography (ultrasound), magnetic resonance angiography, computed tomography, x-ray, computed radiography, nuclear medicine, etc.
Comparison to Predicate:	The intended use and technological characteristics of the Cedara Cardiology Viewer software are substantially equivalent, in the opinion of Cedara Software Corporation to those of the predicate devices and do not pose any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2000

Carol Nakagawa
Manager of Regulatory Affairs
Quality Engineering Support Team
Cedara Software Corporation
6509 Airport Road
Mississauga, Ontario
CANADA L4V 1S7

Re: K002590
Cedara Cardiology Viewer
Dated: August 18, 2000
Received: August 21, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Nakagawa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002590

Device Name: Cedara Cardiology Viewer

Indications For Use :

The Cedara Cardiology Viewer allows qualified medical professionals to capture, retrieve, display, manipulate, measure, report, and save cardiac or other medical images generated by a variety of imaging sources such as X-ray angiography (XA), echocardiography (ultrasound), magnetic resonance angiography, computed tomography, x-ray, computed radiography, nuclear medicine, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

David C. Ayerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT and Radiological Devices
510(k) Number K002590